

***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing Amendment and Reply, claims 1-14 and 17-39 are pending in the application, with claim 1 being the independent claim. Support for the amendment to claim 18 can be found, *inter alia*, at page 10, lines 4-5 of the specification. Support for the amendment to claim 19 can be found, *inter alia*, at page 13, lines 4-10 of the specification. Support for new claims 31-39 can be found, *inter alia*, at page 13, lines 4-10 of the specification. Claim 21 have been amended to correctly italicize *E. coli*. Claims 15 and 16 are sought to be cancelled without prejudice to the subject matter contained therein. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding rejections and that they be withdrawn.

***Double Patenting***

The Examiner rejected claims 1-30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,503,748 B2 (the '748 patent). The Examiner notes that the '748 patent has a common assignee with the instant application even though the inventive entity is different. The Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 and 2 are generic to all

that is recited in claim 1 of the '748 patent. Applicant respectfully traverses this ground of rejection.

Obviousness-type double patenting is a judge-made doctrine that prevents an extension of the patent right beyond the statutory time limit. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d (BNA) 2010, (Fed. Cir. 1993). It requires rejection of an application claim when the claimed subject matter is not patently distinct from the subject matter claimed in a commonly owned patent. See *In re Braat*, 937 F.2d 589, 19 USPQ2d (BNA) 1289, (Fed. Cir. 1991). A double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103" except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967).

As a preliminary matter, Applicant respectfully points out to the Examiner that the '748 patent and instant application are not commonly assigned, and therefore the Examiner is mistaken in noting that a terminal disclaimer will overcome the Examiner's obvious-type double patenting rejection.

Further, Applicant asserts that the Examiner has not established a *prima facie* case that the application claims are not patentably distinct from the patent claims. The Examiner's argument is merely conclusory and rests on the proposition that claims to a genus are necessarily patentably indistinct over a narrower claim in the context of obvious-type double patenting. Applicant respectfully submits that such a proposition is without merit and, moreover, has been refuted by the courts and the Board of Patent Appeals and Interferences. See *e.g.*, *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed.

Cir. 1991). See, also *Ex Parte Michno*, 1993 Pat. App. LEXIS 38, 38 USPQ2d (BNA) 1211 (Bd. Pat. Interferences July 16, 1993), wherein the Board stated "it would appear clear that a mere genus-species or broad-narrow relationship between pending and patented claims is not a litmus test for resolving the question of double patenting of the obviousness type." Thus, the Examiner has failed to establish a *prima facie* case of obvious-type double patenting.

Applicant asserts that the application claims are patentably distinct and non-obvious over the claims in the '748 patent. Specifically, the '748 patent does not disclose, or even suggest that SEQ ID NO:4 or certain fragments thereof comprise a replicon sequence capable of autonomous replication in *Ketogulonigenium* and is silent as to which sequence of the endogenous plasmid is required for replication in *Ketogulonigenium*. Absent Applicant's guidance, the skilled artisan could not have predicted that SEQ ID NO:4 or certain fragments thereof, being removed from the endogenous *Ketogulonigenium* plasmid and joined to heterologous nucleic acids, would confer on the heterologous nucleic acids the property of autonomous replication in *Ketogulonigenium*. Consequently, the claims of the instant application cannot be obvious over claims 1-20 of the '748 patent.

Based on the foregoing, the Applicant respectfully requests that the Examiner reconsider and withdraw the rejection.

#### ***Other Matters***

Applicant respectfully requests that the Examiner consider the document AM3, EP 0278447, which was not initialed by the Examiner on form PTO-1449.

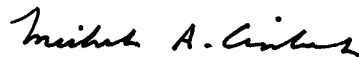
***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Michele A. Cimbala  
Attorney for Applicant  
Registration No. 33,851

Date: Sept. 17, 2003

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600

::ODMA\MHODMA\SKGF\_DC1;178462;1

SKGF Rev. 4/22/03 mac; 6/12/03 svb